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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/549,705

06/23/2006

Dennis N Petrakis

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EXAMINER

SMITH, RICHARD A

ART UNIT

PAPER NUMBER

2859

MAIL DATE

DELIVERY MODE

12/31/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/549,705	Applicant(s) PETRAKIS, DENNIS N	
	Examiner R. Alexander Smith	Art Unit 2859	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 236-253 is/are pending in the application.
- 4a) Of the above claim(s) 237, 239-241, 244, 245, 247 and 252 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 243 is/are allowed.
- 6) ☒ Claim(s) 236, 238, 242, 246, 248-251 and 253 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>20050919 & 20061004</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. The specification is objected to because of the following informalities:

The first paragraph of page 1 under "CROSS REFERENCE TO RELATED APPLICATIONS" is confusing. There appears to be an inconsistency throughout the various applications 09/815,643, 60/454,624, 60/479,481, 60/489,428, 60/508,809 and PCT US04/008338 and their relationships to the current application 10/549,705.

The declaration for the current application states a claim of priority from the PCT and from 60/454,624 while the specification appears to claim a CIP priority from 09/815,643 and 60/454,624, 60/479,481, 60/489,428, 60/508,809 but does not mention the PCT which appears to be between the above priorities claimed and the current application 10/549,705.

The PCT appears to claim priority of 09/815,643, 60/454,624, 60/479,481, 60/489,428 and 60/508,809. The check marked box appears to the examiner as indicating a CIP against all priorities.

The PTO record shows the PCT as having priority from 60/454,624 and 60/479,481 but not from 60/489,428 and 60/508,809.

Therefore there appears to be a discrepancy between the priorities for these documents that need to be addressed or at least straighten out for the current application 10/549,705.

Claim Objections

2. Claims 242, 250 and 251 are objected to because of the following informalities:

Claim 242 is objected to since it is drawn to a self-propelled delivery system however there is no delivery system in the body of the claim. Please note claim 243 and also the

election/restriction requirement wherein the examiner treated the claim as having a delivery system of Group I rather than a self-propelled device of Group III.

Claim 250:

- a. "a fixed volume" in line 1 is confusing because claim 249 appears to state that the shell undergoes a volume change. So if it undergoes a volume change then how can it be fixed?
- b. "a substance" in line 2 does not properly refer to its antecedent in line 3 and lacks consistency with line 7 in claim 248.

Claim 251: "a substance" in line 2 does not properly refer to its antecedent in line 3 of claim 248 and lacks consistency with line 7 in claim 248.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 236 and 238 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,176,575 to Bowie.

Bowie discloses a device and a method which involves:

providing a shell (91); providing a shape memory material activator (96); and deforming the activator in situ by only a single irreversible action while the activator is within a predetermined temperature range, whereby the device is transformed from a dormant state to an active state wherein the activator responds to temperature changes to create a path through the shell to release or admit the substance (as shown).

With respect to "in situ": "In situ" has many definitions depending on the field of use. In this case it appears suitable for Chemistry and chemical engineering, Earth and atmospheric sciences, Environmental engineering and/or, in a broad sense, the basic definition of in the natural place when the natural place is that of a washer.

5. Claim 242 is rejected under 35 U.S.C. 102(b) as being anticipated by JP 5-212093 to Takahashi.

Takahashi discloses a self-propelled delivery system (figures 1-2), comprising: a shape memory material activator (5); work enablers (8) operatively associated with the activator; and at least one track configured with traction means (in a broad sense 15 and 18 with 13), wherein the traction means engages the work enablers to self-propel the activator therealong when the activator is subjected to temperature cycling.

6. Claims 249-251 are rejected under 35 U.S.C. 102(e) as being anticipated by JP 3-100376 to Miwa.

Miwa discloses a shape memory material activated device for allowing the passing of a substance through a shell, the device comprising:

a shell having a volume (2) for containing a substance; and a pressure generator (3) operatively associated with the shell, the pressure generator comprising a shape memory material activator (7) and configured to subject the shell to a pressure cycle while undergoing a volume change during temperature cycling of the shape memory material activator thereby allowing the passing of the substance through the shell (per the arrows in figure 1),

the shell has a fixed volume (the conduit 4 with 5 and 6, and the opening 3a of the shell, are fixed volumes), whereby with each half pressure cycle opens to allow the passing of a substance in a direction determined by the direction of pressure change,

the shell has a variable volume (2), whereby with one half pressure cycle opens (from the dotted 3 to the solid 3 shown in figure 1) to allow the passing of a substance in a direction determined by the direction of pressure change and changes volume during the other half of the pressure cycle.

7. Claim 253 is rejected under 35 U.S.C. 102(e) as being anticipated by US 2004/0024382 to Cho et al.

Cho et al. discloses a system of shape memory material activated substance delivery devices, the system comprising:

a plurality of shape memory material activated substance delivery devices (14), each device comprising at least one shell (about each 14) containing at least a substance and a shape memory material activator configured to release at least the substance at a predetermined temperature (when the release element 28 is an sma, see paragraph 0042), wherein the delivery of each substance, over a temperature range encompassing the release temperatures of the plurality of devices, collectively produces a combined effect (although a combined effect is actually a functional intended result, see paragraphs 0021 and 0038).

Claim Rejections - 35 USC §103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 236 and 238 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2,580,414 to Duffey in view of US 5,176,575 to Bowie.

Duffey discloses a device and a method which involves: providing a shell (1); providing an activator (2, 5, 8, 13); and deforming the activator in situ (when taken as "in vivo" for medical ingestion; and by other definitions for pesticide release) by only a single irreversible action while the activator is within a predetermined temperature range (that whereby water is fluid), whereby the device is transformed from a dormant state to an active state wherein the activator responds to temperature changes to create a path through the shell to release or admit the substance (as shown).

Duffey does not show the activator as being a shape memory material activator by only a single irreversible action while the activator is within a predetermined temperature range.

Bowie discloses a solid capsule wherein a shape memory activator is used to break the capsule. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the capsule and activator, taught by Duffey, to be of a substance which does not readily degrade and to employ a shape memory activator, as suggested by Bowie, in order to provide a release means which is less likely to be affected by moist or fluid environments.

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claim 248 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 18 of U.S. Patent No. 6,682,521. Although the conflicting

claims are not identical, they are not patentably distinct from each other for the following reasons.

US 6,682,521 discloses a shape memory material activated device for controlling the passing rate of a substance through a shell, the device comprising: a shell; a barrier of permeability (via converting a shell wall to a permeable wall); and a shape memory material activator configured to create a path through the shell during temperature changes such that progressive exposure of the barrier occurs thereby permitting the substance to pass therethrough at a rate.

US 6,682,521 claim 1 does not disclose the barrier being of variable permeability and the rate being a changing rate.

US 6,682,521 claim 18 discloses that the release can be variable. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the permeability of the barrier to be variable and with a changing rate in order to provide the proper amount of substance needed relative to time.

Allowable Subject Matter

12. Claim 243 is allowable.
13. Claim 246 would be allowable if the double patenting rejection above is overcome.

14. As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The prior art cited in PTO-892 and not mentioned above disclose related devices, methods and systems.

16. It would be helpful if the Applicant would identify what figures are addressed by all of the elected claims. Further notes are:

It appears to the examiner that claims 249-251 are not describing a capsule type shell but are describing SMA pumps which involve differing class/subclasses from the devices described in the applicant's specification.

It is unclear as to which embodiments are addressed by claims 242 and 243. A text search of the application is not providing a clear indication. Please identify the figures and what are the tracks, the traction means and the work enablers. The examiner is presuming that the tracks are part of the device and are not a separate entity, i.e., blood vessel, intestinal tract, etc. but the only drawings that appear to clearly meet these limitations are the self-propelled vehicles which do not appear to have a drug delivery shell.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to R. Alexander Smith whose telephone number is 571-272-2251. The examiner can normally be reached on Monday through Friday from 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dean A. Reichard can be reached on 571-272-1984. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



R. Alexander Smith
Primary Examiner
Art Unit 2859

December 21, 2007